

The Experience of Conducting Ethical Review during the Ebola Virus Disease Epidemic in Liberia

Jemee K. Tegli, MSc.

UL-PIRE Africa

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Ethics IRB Subjects
Human Monitoring
Compliance Justice
Beneficence Respect
Education Research

Ethics of Clinical Research

- ❑ Why should we do research involving human participants (clinical research)?
- ❑ How should it be done ethically?



Clinical research involves experimenting on humans with the goal of generating useful knowledge and/or remedy about human health and illnesses.

- ✓ Benefit to participants is not the goal/purpose of research (although it does occur).
- ✓ Participants are the means to developing useful knowledge; and are thus at risk of exploitation.

Background: EVD Pandemic in West Africa

- ❑ The Zaire Ebola virus disease (EVD) outbreak In West Africa was first recognised on March 22, 2014 in Guinea.
- ❑ Spread rapidly to Sierra Leone and Liberia; Nigeria, and USA.
- ❑ Without effective interventions, the CDC initially estimated there could be 550,000 to 1.4 million cases of EVD by January 20, 2015.
- ❑ Vaccine trials: Liberia's Ministry of Health (MoH); U.S. Department of Health and Human Services (HHS); GlaxoSmithKline (license rights to ChAd3 experimental vaccine); NewLink (license rights to VSV experimental vaccine), now Merck.

Landmark Interventions

- ❑ Liberia - National Institute Allergy and Infectious Diseases (NIAID)/NIH in 2014.
- ❑ Sierra Leone - London School of Hygiene and Tropical Medicine (LSHTM) in 2015.
- ❑ Guinea - France National Institute of Health and Medical Research (INSERM) in 2015.
- ❑ PREVAC - Liberia, Guinea, Sierra Leone and Mali in 2017.
- ❑ Other players: Medicine San Frontiers (MSF), Clinical RM in 2014
- ❑ Over 10,000 EVD Survivors are now enrolled in several observational studies in Liberia, SL and Guinea.

Was the EVD Outbreak Ethically compelling for clinical trials?

- ❑ Motives scientifically and globally paramount.
- ❑ International Gov't and Research Organizations - WHO.
- ❑ National Governments and Health Ministries.
- ❑ Medicine & Health Regulatory Authorities (MHRAs).
- ❑ Research Ethics Boards (REBs).
- ❑ Public/Community

Critical Ethical Issues Grappled

- ❑ There were plethora of scientific and ethical debates on critical issues on conduction of research during emergencies mounting concerns.
- ❑ The Liberian experience is worth mentioning because the EVD outbreak changed the fragile ethics review structure.
- ❑ IRBs werewhelmed with clinical trials applications between 2014 to 2016.
- ❑ Study design were debatable: RCT, Single arm ring, Stepped-Wedge, etc.
- ❑ DSMB requirement.
- ❑ Studies needed accelerated reviews which placed ethics committees in edgy position.
- ❑ Researchers were in speed to have expedited IRB reviews while some used unconventional means to get approvals.

Ethical Concerns

- ❑ Safety concerns of therapeutics and vaccines candidates and comprehension of the research protocols were daunting.
- ❑ Pre-clinical data prior to review were a challenge.
- ❑ Pls were at times confuse on where to go, i.e., NREB or the Liberian Medicine and Health Regulatory Authority as both were required.
- ❑ Pls were always anxious to initiate studies at all cost as they believe that epidemic was a window of opportunity.
- ❑ Insurance
- ❑ Illiteracy (understanding Vs comprehension)
- ❑ Harm versus benefits
- ❑ Fairness
- ❑ Threats to the Principle of Respect
- ❑ Coercion
- ❑ Undue Inducements
- ❑ Exploitation
- ❑ Therapeutic misconception

Clinical Research Protocols Submissions

- ❑ There were seven trials protocols submitted to two ethics boards in Liberia during the period (2014 - 2016).
 - Clinical trials
 - Several observational Studies
 - Several social behavioral studies
- ❑ The University of Liberia Institutional Review (UL-IRB) Board and the National Research Ethics Board (NREB).
- ❑ Two of these were submitted to the ULIRB and the rest to the NREB. The NREB situated under the Ministry of Health was responsible for all clinical trials while the ULIRB was responsible for all social, behavior and anthropological studies.
- ❑ However, both entities established a collaboration for their members to do joint reviews of all clinical trials protocols.

Public Concerns/Apprehensions and Ethics

- ❑ Ebola outbreak: high levels of fear and mistrust.
- ❑ Conspiracy theories - White man brought it to Liberia.
- ❑ Rumors reflect broader anxieties about medical interventions rooted in histories of exploitation and mistrust.
- ❑ The Trial were attempts to refill a “World Blood Bank.
- ❑ The Presidency, Legislature, Media.
- ❑ Community liaison encouragement of debates to confront anxieties rather than rejecting them as misinformation
- ❑ Was it for Liberia’s good? Or global good? How? Why?

Social Mobilization Communication & Advocacy

The Ethics Boards were also interested in the local cultural setting of protocols.

- ❑ Clinical trial and/or Social science
- ❑ Research-driven communication strategy
- ❑ Community mobilization and engagement
- ❑ Vulnerable stakeholders: EVD Survivors
- ❑ Flyers
- ❑ Rumors tracking and power mapping
- ❑ Media/Press role

Conclusion

- ❑ During the emergency, there were salient ethical issues that emerged from ethics review oversight from structure and composition.
- ❑ The design of trials were tailored towards the safety of the affected population in the best interest of Liberia and humanity.
- ❑ It was observed that trials can be accelerated through structured ethics review process once the requirements are met by researchers.
- ❑ The Liberian experience was a learning curve for the ethical review in the future involving infectious disease research or health emergency involving clinical trials.
- ❑ Share learning within the West African region and abroad will be enhanced.



Medical staff carry an eight year-old suspected Ebola victim into a treatment facility in Monrovia in 2014.



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Thank you for Listening.



Ethics **IRB** **Subjects**
Human **Monitoring**
Compliance **Justice**
Beneficence **Respect**
Education **Research**